

K120161

**510(k) Summary
Prepared January 7, 2011**

APR 13 2012

Sponsor: RadLogics, Inc.
Contact Person: Moshe Becker
Telephone: 408 966 4874
Fax: 408 966 4874
Submission Date: December 6, 2011
Device Name: AlphaPoint Imaging Software

Common Name: Imaging Software

Classification:
Regulatory Class: II
Review Category: Class II
Classification Panel: Radiology
System, Imaging Processing ; 21 CFR 892.2050; LLZ

A. Legally Marketed Predicate Devices

The modified software is substantially equivalent to the Vitrea 2 software manufactured by Vital Images, Inc. and cleared pursuant to K060378.

B. Device Description:

The AlphaPoint system provides a full application framework with integration to PACS using DICOM. The system has the following functions:

- Communicates with PACS to get imaging studies for processing;
- Activates one or more applications that process the imaging data and use segmentation and Hounsfield measurements algorithms to find and measure various attributes in the images, and also identify particular slices as references images for the findings ;
- Formats the processing results for each study into a Preliminary Findings Report
- Sends the results to PACS.
- The software is written in C++, C# and Matlab.

C. Intended Use

The AlphaPoint software is a device that allows review, analysis, and interchange of CT chest images. It is intended for use with CT Chest images to assist medical professionals in image analysis. It is not intended to be the primary interpretation. The software provides segmentation, Hounsfield numerical analysis, and substance indication. The user can review, verify and correct the results of the system and generate a report of the findings.

D. Substantial Equivalence

The submission device is substantially equivalent to the predicate software device with regard to both intended use and technological characteristics. Both devices retrieve and process chest images from Computed Tomography (CT). Both systems are DICOM compliant.

E. Performance Data

The AlphaPoint software has been verified and validated according to the company's design control process. It was tested for compliance with the DICOM Standard and passed the six DICOM specific test cases provided in Section 4.4.4.2 of the Validation Test Report. The software development process complies with FDA Guidance documents related to software in Medical Devices and all of the documents specified have been submitted in the 510(k) Notification and can be summarized as follows

The software development life cycle includes various verification activities and the formal software validation. The software verification activities include design reviews, code reviews, unit tests and system testing.

The Software Test Description (STD) for the Alphapoint System describes the test cases for the device, along with its acceptance criteria, and the detailed test procedure. The test cases in the STD are traced to the requirements found in the SRS. The STD was developed using the template found in the IEEE Std 829-2008, IEEE Standard for Software Test Documentation and J-STD 016 (IEEE STD 1498), Software Development and Documentation.

The validation test runs were documented in the Software Test Report (STR) for the Alphapoint System. The STR contains the date, tester name, software versions, specific configurations used in the testing and the Pass/Fail grade for each test procedure step. The STR summarizes the validation assessment, which states that the software is ready for release. The STR was developed using the template found in the IEEE Std 829-2008, IEEE Standard for Software Test Documentation and J-STD 016 (IEEE STD 1498), Software Development and Documentation.

The validation was performed by a qualified independent software validation engineers who were not directly involved in the software design and implementation efforts. All anomalies have been resolved.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

RadLogics, Inc.
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Accredited Third Party Reviewer
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1394 25th Street, NW
BUFFALO MN 55313

APR 13 2012

Re: K120161

Trade/Device Name: AlphaPoint Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 20, 2012
Received: February 21, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

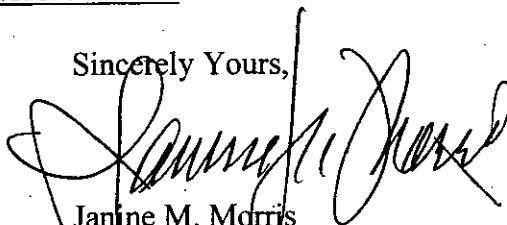
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris
Acting Director

Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: AlphaPoint Imaging Software

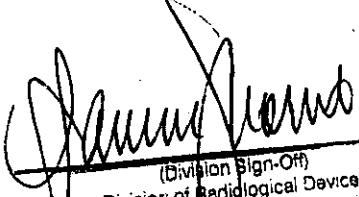
Indications for Use:

The AlphaPoint software is a device that allows review, analysis, and interchange of CT chest images. It is intended for use with CT Chest images to assist medical professionals in image analysis. It is not intended to be the primary interpretation. The software provides segmentation and Hounsfield numerical analysis values which are indicative of various substances (i.e., air, lung, soft tissue, fat, water, transudate, exudate, blood, muscle and bone). The user can review, verify and correct the results of the system and generate a report of the findings.

Prescription Use AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
K12016
510K